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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,791	11/14/2003	Stefan Willmann	Bayer 10263-WCG	2985
27386	7590	08/18/2008		
NORRIS, MC LAUGHLIN & MARCUS, P.A.			EXAMINER	
875 THIRD AVE			ZEMAN, MARY K	
18TH FLOOR			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/714,791	<b>Applicant(s)</b> WILLMANN ET AL.
	<b>Examiner</b> Mary K. Zeman	<b>Art Unit</b> 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 April 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments filed 4/30/08 have been fully considered but they are not persuasive.

Claims 1-27 are pending in this application.

#### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-27 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims have been amended. Claim 1 has been amended to recite an input-output module which in part is to output "simulated concentration/time profiles". Claim 10 has been amended to recite in part: "outputting the predicted concentration/time profile to a user". The media of claim 19 has been amended in part to read "a transportable media" and an output step.

Claims 1-9 are drawn to computer "systems" which execute certain method steps. The method steps performed by the system "for predicting" profiles or parameters are not a concrete tangible and useful result. While the claim has been amended to incorporate limitations to physical system elements, the method performed by the system still does not produce a concrete, tangible and useful result. The "concentration/time profile" appears to be a graph, or data series which requires significant further interpretation to be used. Claims 10-19 are drawn to methods which do not provide a physical transformation of matter, nor do they provide a concrete, tangible and useful result. The result of the method of claim 10 is a "simulation" which is not clearly obtained in all cases (concrete), and is not immediately useful. The "simulation" requires further manipulation and interpretation to be used. Claims 19-27 are drawn to digital storage media which carry out a method which is non-statutory. Further, there is not limiting definition of "transportable digital storage media" such that the term can be broadly construed to cover non-statutory storage media such as carrier waves and wireless storage.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, (and 10 and 19,) the metes and bounds of the limitations of the modules are unclear. Applicant's arguments have been fully considered, but are not persuasive. It is noted that the features upon which applicant relies (the disclosure of the equations and data which make up the models and modules) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claim refers to element 102, which is a box in figure 1, is totally lacking in any description as to what the model encompasses. The specification at page 4 fails to provide a specific definition of the model and says it "involves physiological parameters which depend only on the type of insect to be described as well as one or more substance-dependent parameters." The specification page 6 discloses further information about a model with reference to Figure 3, which does not set forth element 102. It is entirely unclear what parameters are to be used and how the parameters are to depend on the substance. Further, the prediction module is similarly indefinite as the specification is totally lacking in the elements of such a module of 110. How a single substance -based- parameter can drive a simulation and prediction according to the claim is not set forth in positive active steps in the claim nor the specification. It is further unclear in description of "a parameter". It would appear the system already has the parameter that is to be predicted, which is circular and indefinite.

Claims 2-5 fail to remedy the deficiencies in claim 1. Claim 6 is unclear, as it is not clearly set forth whether the QSAR model or neural network is present in the system of claim 1. In claim 7, it is unclear parameters are “used” to obtain other functions or predictions. Claims 8 and 9 fail to remedy the deficiencies of claim 1.

Claims 10 and 19 are structurally similar in setup to claim 1 and have similar deficiencies. Claim 10 fails to set forth positive active steps by which the methods is to be specifically performed. Claims 11-18 and 20-27 do not remedy these problems.

Regarding claim 10, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The amendments to claim 19 are unclear, as the “outputting” step does not make sense in the context of the transportable storage media. It would appear this is intended to be either a means for outputting, or to somehow model the simulation means. It is unclear which.

Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection. The amendment to claim 19 to recite a “transportable” digital storage media is new matter. The specification fails to provide any support for any element of a transportable storage media, and applicant did not point out any support in the originally filed specification for such a limitation. The amendment was made in an attempt to overcome a rejection under 35 USC 101, however, the amendment lacks support and is new matter. The amendments to “Means for” and “simulations means” also lack basis and are addressed below.

Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 recites various “means for” clauses. The “mean for inputting” and “simulation means” lack specific related structures in the specification. No specific structures for performing these means are disclosed. See MPEP 2181: 35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.” “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)... Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. 112, first paragraph. See In re Noll, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976) (unless the means-plus-function language is itself unclear, a claim limitation written in means-plus- function language meets the definiteness requirement in 35 U.S.C. 112, second paragraph, so long as the specification meets the written description requirement in 35 U.S.C. 112, first paragraph)... the invocation of 35 U.S.C. 112, sixth paragraph, does not exempt an applicant from compliance with 35 U.S.C. 112, first and second paragraphs. See Donaldson, 16 F.3d at 1195, 29 USPQ2d at 1850; Knowlton, 481 F.2d at 1366, 178 USPQ at 493.

Claims 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, Applicant’s recitation of “mean for inputting” and “simulation means”, has invoked the special claim interpretation provisions of 35 USC 112 sixth paragraph. In turn, claim 19 is rejected under 35 USC 112 second paragraph.

In order for a claim to meet the particularity requirement of 35 USC 112 second paragraph, the corresponding structure(s) of a means-plus-function limitation must be disclosed in the written description in such a manner that one skilled in the art will know and understand what structure corresponds to the means limitation.

Regarding the means-plus-function limitations recited in the instant claim, i.e., “mean for inputting” and “simulation means”, there does not appear to be any structure in the specification corresponding to these means-plus-function limitations in the claims.

Therefore, “[i]f there is no structure in the specification corresponding to the means-plus-function limitation in the claims, the claim will be found invalid as indefinite.” *Biomedino LLC v. Waters Technologies Corp.*, 83 USPQ2d 1118, 1121 (Fed. Cir. 2007).

Applicant is reminded that any amendment must point to a basis in the specification so as not to add New Matter. See MPEP 714.02 and 2163.06.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjic Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Mary K Zeman/

Primary Examiner, Art Unit 1631